

STATE OF MICHIGAN
DEPARTMENT OF ENERGY, LABOR & ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXXX

Petitioner

v

File No. 120340-001

Time Insurance Company
Respondent

Issued and entered
this 10TH day of October 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On March 30, 2011, XXXXX (Petitioner) filed a request for an external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner is covered under an individual medical policy that is underwritten by Time Insurance Company. The Commissioner immediately notified Time of the external review and requested the information it used to make its final adverse determination. The Commissioner received Time's response on March 31, 2011.¹ On April 8, 2011, after a preliminary review of the material submitted, the Commissioner accepted the case for external review.

The case involves medical issues so the Commissioner assigned the matter to an independent review organization which sent its recommendation to the Commissioner on April 22, 2011.

¹ Assurant Health, which markets Time's products, responded on Time's behalf.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in a certificate of medical insurance (the certificate) issued by Time.

On September 13 and September 14, 2010, the Petitioner received stanozolol and nandrolone injections administered by his physician. Time denied coverage for the injections on the basis that they were experimental and investigational for the treatment of the Petitioner's condition.

The Petitioner appealed the denials through Time's internal grievance process. Time upheld its denial and issued a final adverse determination on March 14, 2011.

III. ISSUE

Did Time correctly deny coverage for the Petitioner's stanozolol and nandrolone injections?

IV. ANALYSIS

Respondent's Argument

Time had the Petitioner's records reviewed by a medical expert and then explained its decision to deny coverage for the stanozolol and nandrolone injections in its final adverse determination:

The clinical rationale for the decision is:

The patient had blood work performed prior to seeing [his physician]. Laboratory study results included the following: thyroid antibodies normal, random serum testosterone 413 ng/dl, PSA (prostate-specific antigen) normal, IGF-1 (insulin-like growth factor 1) 95 ng/mL (low), SHBG (sex hormone-binding globulin) 38.1 (high), Estradiol, FSH (follicle-stimulating hormone), LH (luteinizing hormone), TSH (thyroid-stimulating hormone), free T-4, reverse T3, free T-3 and DHEA-Sulfate all normal.

The [Petitioner] saw [his physician] on 4/12/2010 for complaints of "insomnia, poor workouts, no libido, erectile dysfunction and fatigue." The record notes that the [Petitioner] "is aware of the benefits of testosterone and HGH and is here for suggestions for treatment." The record documents that the [Petitioner] complained of depression. The physical exam does not document a genital or a rectal exam. The evaluation does not document a differential diagnosis. [Petitioner's physician] initiated androgen therapy with Nandrolone, Testosterone and Stanozolol.

A follow up note documented that the [Petitioner] reported that he “feels great” at his next visit on 4/19/2010. The record did not document a genital or rectal exam. A new pulse and blood pressure were recorded. The remainder of the noted was copied from the evaluation of the previous week.

Subsequent follow up notes did not document a genital or rectal exam. Oxandrin was added on 9/13/2010. A rise in the [Petitioner’s] Estradiol was addressed with a recommendation to take Tamoxifen on 11/3/2010.

[The physician’s] appeal correspondence cites the position statement by the Endocrine Society. The conclusions include the following: “We recommend making a diagnosis of androgen deficiency only in men with consistent symptoms and signs and unequivocally low serum testosterone levels. We suggest the measurement of morning total testosterone level by a reliable assay as the initial test. We recommend confirmation of the diagnosis by repeating the measurement of morning total testosterone and, in some men in whom total testosterone is near the lower limit of normal or in whom SHBG abnormality is suspected by measurement of free or bioavailable testosterone level, using validated assays. We recommend against starting testosterone therapy in patients with . . . a palpable prostate nodule . . . without further urological evaluation . . .”

The record does not document any consideration of whether depression might be the underlying cause of the patient’s nonspecific symptoms. The record does not document examination for physical signs of androgen deficiency. The record does not document any physical assessment of the prostate gland. The record does not document measurement of morning testosterone or free testosterone levels. The single random testosterone level of 413 ng/dL (that was obtained before initiating therapy) is not low.

* * *

A diagnosis of hypogonadism is not supported by the submitted medical records and laboratory results. Androgen therapy of a patient without established signs and symptoms of androgen deficiency confirmed by reliable laboratory testing is experimental and investigational as the peer reviewed medical literature does not contain statistically valid randomized controlled studies demonstrating improved clinical outcomes in patients with nonspecific complaints of decreased sexual function, insomnia and fatigue who have random testosterone levels greater than 400 ng/dL. The long term safety of treating men who do not have demonstrated androgen deficiency with multiple androgenic compounds has not been established.

The previous decision to deny coverage is upheld. There are no documented physical findings suggesting hypogonadism. There are no lab findings that demonstrate hypogonadism or androgen deficiency. In the absence of a laboratory

confirmed diagnosis of hypogonadism or androgen deficiency, the use of injectable androgens (Nandrolone, Oxandrin, Stanozolol and Testosterone) and Tamoxifen for the treatment of nonspecific symptoms and the side effects of androgen therapy is experimental and investigational.

Petitioner's Argument

In a March 16, 2011, letter to Time, the Petitioner's physician objected to the conclusion of Time's medical expert that the stanozolol and nandrolone injections were experimental or investigational:

The Endocrine Society States: "where SHBG abnormality is suspected by measurement of free or bioavailable testosterone levels" IS the Free Androgen Index (FAI) as published by DC Anderson in 1972 in Nature. The normal Free Androgen Index is greater than .7 as Anderson defined normal SHBG to be between 5 and 15. High SHBG lowers Free Testosterone. The proven data from [the Petitioner] showed his FAI to be well below normal.

Now, he had prostate examinations from other doctors. Your physician is again misinformed: hypogonadism is a clinical diagnosis while "low Levels of testosterone" is a laboratory test. They are interchangeable in standard medical practice.

Your only point is to claim that the use of testosterone, available in the United States as injectable testosterone cypionate is somehow, 'experimental.' . . .

* * *

Please reconsider your action.

Commissioner's Review

The certificate (pp. 51, 55) excludes coverage for services that are experimental or investigational:

IX. EXCLUSIONS

We will not pay benefits for any of the following:

* * *

38. Charges Incurred for Experimental or Investigational Services.

The certificate (p. 15) defines experimental or investigational services as:

Treatment, services, supplies or equipment which, at the time the charges are Incurred, We determine are:

1. Not proven to be of benefit for diagnosis or treatment of a Sickness or an Injury; or
2. Not generally used or recognized by the medical community as safe, effective and appropriate for diagnosis or treatment of a Sickness or an Injury; or
3. In the research or investigational stage, provided or performed in a special setting for research purposes or under a controlled environment or clinical protocol; or
4. Obsolete or ineffective for the treatment of a Sickness or an Injury; or
5. Medications used for non FDA approved indications and/or dosage regimens.

Because of the medical issue involved, this case was assigned to an independent review organization (IRO) to determine if the stanozolol and nandrolone injections are experimental or investigational for treatment of the Petitioner's condition. The IRO reviewer is a practicing physician who is board certified in internal medicine, endocrinology and metabolism. The IRO report contains the following analysis:

The MAXIMUS independent physician consultant, who is familiar with the medical management of patients with the [Petitioner's] condition, has examined the medical record and the arguments presented by the parties.

The results of the MAXIMUS physician consultant's review indicate that this case involves a 39 year-old male who has a history of insomnia, poor workouts, lack of libido, erectile dysfunction and fatigue. At issue in this appeal is whether stanozolol and nandrolone injections are experimental/investigational for treatment of the [Petitioner's] condition.

The MAXIMUS physician consultant noted that initiation of testosterone replacement has become prevalent in the treatment of men with hypogonadism to ameliorate potential complications. The MAXIMUS physician consultant also noted that in order to initiate therapy for hypogonadism, this diagnosis must first be made. The MAXIMUS physician consultant explained that a patient must have a medical history and physical examination that are consistent with hypogonadism as well as a morning total testosterone of less than 300 ng/dl for a diagnosis of hypogonadism to be made. [Citation omitted] The MAXIMUS physician consultant also explained that the [Petitioner] does not fulfill these criteria. Therefore, the MAXIMUS physician consultant indicated that testosterone replacement with stanozolol and nandrolone is not medically indicated for treatment of the [Petitioner's] condition.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that stanozolol and nandrolone injections are experimental/investigational for treatment of the [Petitioner's] condition.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on extensive experience, expertise and professional judgment. The Commissioner can discern no reason why the IRO's recommendation should be rejected in the present case.

The Commissioner concludes and finds that Time's denial of coverage for the Petitioner's stanozolol and nandrolone injections was consistent with the terms of the certificate.

V. ORDER

The Commissioner upholds Time Insurance Company's March 14, 2011, final adverse determination. Time is not required to cover the Petitioner's stanozolol and nandrolone injections.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.